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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,547	12/05/2003	Ronald W. Marsh	P-4154PIC1	8789
26253 7590 04/15/2008 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company 1 Becton Drive MC 110 Franklin Lakes, NJ 07417-1880				
EXAMINER				
GRAY, PHILLIP A				
ART UNIT		PAPER NUMBER		
3767				
MAIL DATE		DELIVERY MODE		
04/15/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/728,547

**Applicant(s)**

MARSH ET AL.

**Examiner**

Phillip Gray

**Art Unit**

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This office action has been reopened to add new rejections to the claims as currently written.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Chu et al. (U.S. 5,397,310). Chu discloses a catheter introducer sheath assembly and discloses a needle (as shown in figures 11-15) comprising an elongate tube (120) with sharpened tip, a hub (near 2a or 4 as in figure 3) and a resilient member (22 shown in figure 3) and a clamp (12/24 as in figure 3), and where the clamp is in an open position (4 or 4b) and a clamp position (shown in figure 4a wherein "the clamp causes a strain to at least a portion of the resilient member thereby **reducing but not occluding**, the inner diameter of the opening through at least a portion of the resilient member", further a spinal needle (124) is shown whereby the spinal needle may become fixed but not occluded (see figure 11a)

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over McWha et al. (U.S. Patent Number 5,480,389) in view of Schaffer (U.S. Patent Number 5,429,616). McWha discloses a spinal epidural needle set (figure 3) comprising an elongate tube (14) with a sharpened distal end (15), an attached hub (22,26,34,51,40) and a spinal needle (12) and indicia for location (34). The epidural and spinal needle system is fully capable of performing all the associated functional language and claim limitations. Schaffer discloses a hub/needle/catheter (see figures 2 and 5) with a resilient member (50) permanently mounted within a hub (26), and a deformable U-shaped clamp with living hinge (24) with a releasable latch push tab (60) and support arms, that is oriented for perpendicular movement to the elongate tube. Further the

resilient member defines a radiused portion and the readiused portion of the pair of legs (48) has a radius substantially the same as the radiused portion of the resilient member, and a second radiused portion (figures 3-6). The resilient member and clamp of Schaffer are fully capable of performing all the associated functional language and claim limitations.

Mc Wha discloses the claimed invention except for the resilient member and clamp. Schaffer teaches that it is known to use a resilient member and clamp as set forth in paragraphs beginning at columns 1-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the epidermal needle system as taught by Mc Wha with the resilient member and clamp as taught by Schaffer, since such a modification would provide the epidermal needle system with the resilient member and clamp for providing inward collapsing of the side wall portion and to **reduce but not occlude** the apparatus.

Concerning the newly amended claim language that the clamp causes a "strain to at least a portion of the resilient member thereby **reducing but not occluding**...", It is examiners position that the resilient member and clamp of Schaffer would be fully capable and known (to a PHOSITA) that the clamp would **reduce but not occlude** the inner diameter of the opening. As evidenced in figures 3 through 6 of Schaffer, the clamp has a range of operation that causes the inner diameter to be from fully open to occluded, but also has an intermediary position of a "reduced" in diameter state (when not fully open or fully closed). Therefore it is examiners position that the clamp would be fully **capable of reducing but not occluding**.

In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the clamp reduce the inner diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955). In this case it would be obvious for a person having ordinary skill in the art at the time of the invention, to modify the range of the clamp (how closed it becomes or how much it reduces the inner diameter) in order to limit the amount of fluid flow through an inner diameter or reduce the space to secure the clamp to another body.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PAG

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767